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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,727	09/29/2006	Yasushi Ito	1027550-000895	9393
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EXAMINER				
OSINSKI, BRADLEY JAMES				
ART UNIT		PAPER NUMBER		
3767				
NOTIFICATION DATE		DELIVERY MODE		
08/06/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

### Office Action Summary

**Application No.**

10/594,727

**Applicant(s)**

ITOU ET AL.

**Examiner**

BRADLEY J. OSINSKI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5, 7, 8 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7, 8 and 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 5-21-2009 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3, 5, 7, 8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoste (6,508,806) in view of Bazaral (4,925,448) and Van Es (5,501,341).

a. Regarding claims 1-3, Hoste discloses an angiographic catheter with a lumen and stainless steel metal reinforcement embedded within the wall to vary catheter pitch (Col.3 lines 5-14) and the length of the catheter being 80-125 cm for coronary angioplasty. The catheter thus has distal and proximal portions of 40-62.5 cm in length. The stainless steel mesh of Hoste inherently makes the device highly susceptible to plastic

deformation (see page 14, paragraph 35 of the instant application). Hoste further discloses a shaped distal end, such as a J-shape in the natural state in order to facilitate entry into the ostium (Col.4 lines 19-21). Additionally, disclosed is a connector part fixed to the proximal portion of the catheter body.

While Hoste substantially discloses the invention as claimed, it does not disclose the states in which the catheter is held in a packaging.

However, Bazalal discloses a proximal portion held in a curved state by the compartment and is covered by a plastic impermeable to microorganisms and particles. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to enclose the proximal half of Hoste in a plastic compartment/tray as disclosed by Bazalal to keep the distal portion protected from microorganisms and particles while the proximal portion is being attached to the appropriate machines.

Van Es discloses the distal half held on a card in its natural state so that the catheter is not damaged as it is withdrawn from the plastic/tray. It would have been obvious to one of ordinary skill in the art to hold the distal end in its natural state so that as the catheter is withdrawn, the distal end is not damaged.

b. Regarding claims 5, 7 and 8, While Hoste substantially discloses the invention as claimed, it does not disclose the catheter spanning two trays removably integrated with each other. However, Bazalal discloses a

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catheter spanning two trays as in figure 1 integrated into one package, but separated by different plastic films (figure 7). Therefore, it would have been obvious to one of ordinary skill in the art to use the trays of Bazaral so that the distal and proximal sections remain separate so that the other section remains protected microorganisms and particles while the other section is being setup/used. Regarding the removable part specifically, this is not seen as limiting as anything is capable of being tom/destroyed.

c. Regarding claim 10, see claim 1 above, the package of Bazaral has a bottom and upstanding walls as can be seen in figures 2 and 4.

d. Regarding claims 11 and 12, the different sections of Bazaral comprise a plurality of separate trays (separated by the walls, such as 102 and 112) that are back to back with each other and have cutouts (such as 113, 103 and 107).

### ***Response to Arguments***

2. Applicant's arguments filed 5-4-2009 have been fully considered but they are not persuasive.

e. Applicant argues that the recited combination teaches away from each other. More specifically because Hoste discloses a catheter with a wire reinforcement and Bazaral has a catheter that deals with catheters without wire reinforcement. However, upon rereading the references, the Examiner finds nothing in either specification teaching away from the recited combination.

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f. Applicant argues that impermissible hindsight is used. However, every catheter needs to be packaged, and one is not provided by Hoste. Additionally, the reasons for combining the references are provided in the specifications of the secondary references themselves (abstract of Bazaral and Col.1 lines 46-59 of Vas Es).

***Allowable Subject Matter***

3. The amendments to claims 5, 7 and 9 are not seen as patentably distinct as anything is capable of being removed relative to something else (in this case torn/destroyed). Applicant is advised that structure drawn to how the trays are removable/separable from each other would be seen as an area of possible allowable subject matter.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/  
Examiner, Art Unit 3767  
/Kevin C. Simmons/  
Supervisory Patent Examiner, Art Unit 3767